

### REMARKS

In the Office Action dated August 2, 2007, the Examiner contends that a Restriction Requirement between one of the following inventions is required under 35 U.S.C. §121 and 372:

Group I - Claims 1-8, drawn to an excipient system for an active substance, consisting of at least one carrier molecule from the group of calixarenes and resorcinarenes; and

Group II – Claim 9, drawn to a method of use of calixarenes and resorcinarenes as excipient systems for active substances.

In compliance with the August 2, 2007 restriction requirement, Applicant herein elects what the Examiner identified as Group II – claim 9 drawn to a method of use of calixarenes and resorcinarenes as excipient systems for active substances without traverse. Claims 2 – 9 read on the elected species. In compliance thereof, Applicant withdraws from examination claim 1 without prejudice.

The Examiner also contends that the species claimed in the invention lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species to which the Examiner refers are as follows:

1. Calixarenes contained within Formula 1, claim 1
2. Resorcinarenes contained within Formula 2, claim 1; and
3. A mixture of calixarenes and resorcinarenes, contained within Formula 1 and 2 respectively, claim 1.

In compliance with the August 2, 2007 restriction requirement, Applicant herein elects the following species with traverse: Calixarenes contained within Formula 1, claim 1

Claims 10 - 17 read on the elected species. R is specified as a alkyl, aryl, alkoxy, or aryloxy; R1 is specified to be an azophenyl dye; X is specified as methylene; and m = 4, 5, 6



or 8. These have been specified at the request of the Examiner, again **with traverse**.

The Restriction Requirement is traversed on the grounds the Examiner has not demonstrated that a serious burden would be imposed if restriction is not required, and thus has not established a *prima facie* case for requiring restriction.

Every requirement for restriction must include a showing that (1) the inventions are either independent or distinct as claimed; and (2) that there would be a serious burden on the examiner if restriction is not required. (See MPEP § 803(I)). Reasons (as distinguished from merely stating a conclusion) why each invention is either independent or distinct must be presented, and well as reasons why there would be a serious burden on the examiner if restriction is not required. (See MPEP § 808). To demonstrate a "serious burden" the examiner must show by appropriate explanation that either (1) the inventions are separately classified; (2) the inventions have formed a separate status in the art even though they are classified together; or (3) the inventions will require a different field of search. (See MPEP § 808.02).

The requirements for restriction are applicable to election of species as well as other types of restrictions. In instances where there is no disclosure of relationship between species, they are considered independent inventions and a requirement for restriction would be permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if restriction is not required. (See MPEP § 808.01(a)). Once again, to establish a "serious burden", the examiner must show by appropriate explanation one of the three conditions set forth in MPEP § 808.02 (i.e., separate classification, separate status in the art when they are classified together, or a different field of search). (See MPEP § 808.01(a)). On the other hand, where the inventions as disclosed and claimed are both species under a claimed genus and related, whether restriction is proper must be determine by both the practice applicable to election of species and the practice applicable to other types of restrictions. (See MPEP § 806.04(b)). If restriction is improper under either practice, it should not be required. *Id.*



In the present case, the Examiner contends that the identified species are either independent or distinct because they are structurally different compounds. Even assuming for the sake of argument that is true, the Examiner has nevertheless not provided any evidence to establish that examining each of the species would impose a serious burden. Indeed, the present restriction requirement does not include any discussion at all regarding any of the three conditions for establishing a "serious burden" under MPEP § 808.02.

The Examiner contends that calixarenes and resorcinarenes are structurally different compounds. The Applicant respectfully disagrees, in so far as any differences would create any additional burden on the Examiner. Resorcinarenes are a functional subset of calixarenes. For examples of support, please refer to the cited reference Tetrahedron, 52(8), 2662-2704 (1996) in addition to the following: *Characterization of calixarene- and resorcinarene-bonded stationary phases. I. Hydrophobic interactions*, J Chromatogr A, 2003 Dec 22; 1021(1-2):71-82; *Separation of cis- and trans-isomers of thioxanthene and dibenz[b,e]oxepin derivatives on calixarene- and resorcinarene-bonded high-performance liquid chromatography stationary phases*, J Chromatogr A, 2002 Mar 1; 948(1-2):309-19; *Gas-phase interactions of calixarene- and resorcinarene-cavitands with molecular guests studied by mass spectrometry*, International Journal of Mass Spectrometry, Volume 214, Number 1, 15 February 2002, pp. 23-36(14). Claims 2-9 have been amended to more clearly define the carrier of the excipient system.

The Examiner further is requiring the election of single disclosed subspecies: in Formula I, R1, R, X and m; and in Formula II, R, R1, R2, R3, R4 and r. The Applicant respectfully contends that this restriction is an improper restriction of Markush groups. Proper Markush groups must contain compounds with common functions while recognizing that in any Markush group the compounds "will differ from each other in certain respects." *In re Jones*, 74 USPQ 149 (1947). The compounds must be a subgenus which is not repugnant to scientific classification. *In Re Horst Harnisch*, 206 USPQ 300 (1980). The materials set forth in the



Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. When the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly reasonable for their function in the claimed relationship, and it is clear from their nature or from the prior art that they possess this property. MPEP 803.02. The Applicant respectfully submits that the Markush groups in claim 9 are proper and should not be restricted.

The Applicant has made a good faith effort to respond to the Examiner's restrictions requirements. Although the restriction of the Markush groups is traversed, Applicant has made every effort to comport claim 10 to the Examiner's request.

Applicant respectfully requests that the present requirement for restriction between Formula I, Formula II and Formulas I and II be withdrawn. Reconsideration of the application as amended is requested. It is respectfully submitted that this Amendment places this application in suitable condition for allowance; notice of which is requested.

Respectfully submitted,



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